

REMARKS

This submission is made concurrently with the Request for Continued Examination of this Application.

The present invention discloses a process for drying an aqueous solution of uncomplexed modified cyclodextrin on a drum dryer. In one of the novel aspects of the invention, the aqueous cyclodextrin solution has a solids content of between about 5 to about 70% by weight. The process of the invention provides a cyclodextrin product that has superior dusting properties and dissolution in water properties compared to cyclodextrin products dried using conventional drying processes. Specifically, the dried cyclodextrin product has a desirable particle size distribution and a dissolution time in water less than about 5 minutes at 75°F and 10% solids.

Applicants have amended claim 7 in order to more particularly define the invention. Specifically, claim 7 has been amended to recite the solids content of the aqueous cyclodextrin solution and to recite the dissolution time of the product. Support for the solids content can be found on page 6, lines 10-12. Support for the dissolution

time can be found in claim 19. Claims 11 and 19 have thus been cancelled.

Claims 7-9 and 19 had been rejected as being unpatentable over Shah in view of Walsh or Giacobello. Claims 12, 13 and 15-18 had been rejected as being unpatentable over Shah.

Shah had been cited to teach drying techniques for sulfoalkyl ether cyclodextrins. Shah states that suitable drying techniques are freeze drying, spray drying and vacuum drum drying. The Examiner had equated the vacuum drum drying of Shah with the drum drying of claim 7.

Applicants submit that the present invention is not obvious from the teachings of Shah because:

- (1) one of skill in the art is not taught to select drum drying and the specific drying conditions of the invention based on the teachings of Shah; and
- (2) Shah teaches away from the aqueous solution solids content of the invention.

Shah is concerned with a production method for sulfoalkyl ether cyclodextrins using alkyl sultone and a

base (col. 2, lines 9-20). Shah recites a list of suitable drying techniques for the aqueous sulfoalkyl ether cyclodextrin product (col. 3, lines 13-26). The Examiner has recognized that Shah does not specifically teach drum drying as recited in claim 7.

The Examiner had stated that it would be obvious to substitute the vacuum drum drying of Shah for the drum drying of the invention. Applicants respectfully disagree.

Shah is not concerned with a novel method for drying an aqueous cyclodextrin. Shah does not mention any specific drying conditions, nor does Shah list any preferred drying technique. Shah lists a total of 5 drying techniques: freeze drying, spray drying, vacuum drum drying (col. 3, lines 25-26), evaporation using a Buchii apparatus (Example 1) and evaporation using a rotary evaporator (Example 5). It appears that these drying techniques can be interchangeably used. Clearly, the Examiner will appreciate that Shah does not teach a preferred drying technique. In fact, it appears that Shah equates each of the 5 drying techniques, since Shah interchangeably uses Buchii drying (Example 1), freeze drying (Example 3) and rotary evaporation (Example 5) throughout the Examples.

Furthermore, Shah does not teach any specific process conditions for the 5 drying techniques. Shah does not teach the advantages of drying an aqueous solution of cyclodextrin having a solids content of as recited in claim 7. As pointed out by Mr. Sikorski in his Declaration of September 10, 2003, the specific drying conditions of the invention lead to a desirable dried cyclodextrin product compared to a spray dried cyclodextrin. Mr. Sikorski has therefore demonstrated the advantages of the present invention compared to 1 of the 5 drying techniques that Shah equates and interchangeably uses.

In addition, Shah teaches away from the solids content of claim 7. Example 1 of Shah contains 400g of beta-cyclodextrin (col. 7, lines 15-17). The entire reaction mixture is diluted with water to 14 kg before drying (col. 7, lines 39-40). Thus, Example 1 of Shah contains 2.86% cyclodextrin by weight. In contrast, claim 7 recites a solids content of between about 5 to about 70%. Shah therefore teaches away from the solids content range of claim 7.

Applicants therefore submit that one of skill in the art would not find it obvious to arrive at the present invention from the teachings of Shah because:

- i) there is no teaching or suggestion in Shah to select drum drying since Shah does not specifically teach drum drying;
- ii) there is no teaching or suggestion in Shah to select vacuum drum drying (stated by the Examiner to be equivalent to drum drying) out of the 5 total drying techniques of Shah;
- iii) there is no teaching or suggestion in Shah to drum dry an aqueous solution of cyclodextrin having a solids content of about 5 to about 70% by weight;
- iv) Applicants have demonstrated that drum drying is superior to spray drying, while Shah equates spray drying and vacuum drum drying; and
- v) Shah teaches away from the solids content of the present invention.

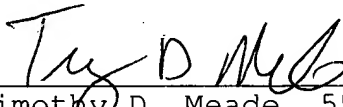
Walsh and Giacobello have been cited to teach the operational ability for drum drying apparatuses. Applicants submit that the present invention is patentable over the teachings of Shah, Walsh and Giacobello taken alone or in combination.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. A two-month extension of time is requested and PTO Form 2038 is enclosed herewith authorizing payment of the appropriate government fee. Should any further fees or extensions of time be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit Account # 02-2275.

Respectfully submitted,

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